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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,836	11/25/2003	Dwayne Lee Looney	ETH-5112	7733
27777	7590	02/20/2007		
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER GHALI, ISIS A D	
			ART UNIT	PAPER NUMBER
			1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/721,836	Applicant(s) LOONEY ET AL.	
	Examiner Isis A. Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/25/2003, 03/15/2004, 06/28/2004, 10/28/2004, 01/24/2005, and 08/11/2005.

DETAILED ACTION

The receipt is acknowledged of applicants' IDSs filed 11/25/2003, 03/15/2004, 06/28/2004, 10/28/2004, 01/24/2005, and 08/11/2005.

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 10/326,244. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: hemostatic wound dressing comprising fabric comprising aldehyde modified polysaccharide and polymeric porous matrix comprising water-soluble water-swellaable proteinaceous polymer. Aldehyde modified polysaccharide is recited by instant claim 9 and proteinaceous polymer is recited by claim 22 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/448,878 in view of US 4,948,450 (540). The present claims and the conflicting claims are directed to hemostatic wound dressing comprising

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fabric comprising oxidized regenerated cellulose and polymeric porous matrix comprising water-soluble water-swellaable polymer.

The difference between the present claims and the conflicting claims of the copending application is that the conflicting claims do not recite the water-soluble water-swellaable polymer as proteinaceous polymer.

US '540 teaches mechanically stable comfortable wound dressing of porous non-cross-linked collagen material (protein claimed by applicants) that exhibits high absorptivity that makes it useful as surgical and medical dressing (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide hemostatic wound dressing comprising fabric comprising oxidized regenerated cellulose and polymeric porous matrix comprising water-soluble water-swellaable polymer as claimed by application 10/448,878, and replace the porous water-soluble water-swellaable polymer matrix by porous collagen material disclosed by US '540, motivated by the teaching of US '540 that porous collagen material are useful as surgical and medical dressing because it is mechanically stable comfortable and has high absorptivity, with reasonable expectation of having hemostatic wound dressing comprising fabric comprising oxidized regenerated cellulose and collagen porous matrix wherein the dressing is mechanically stable comfortable and highly absorptive.

This is a provisional obviousness-type double patenting rejection.

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5. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 7-11 of copending Application No. 10/396,226 in view of US 4,948,450 (540). The present claims and the conflicting claims are directed to hemostatic wound dressing comprising fabric comprising oxidized regenerated cellulose and polymeric porous matrix comprising water-soluble water-swellaable polymer.

The difference between the present claims and the conflicting claims of the copending application is that the conflicting claims do not recite the water-soluble water-swellaable polymer as proteinaceous polymer.

US '540 teaches mechanically stable comfortable wound dressing of porous non-cross-linked collagen material that exhibits high absorptivity that makes it useful as surgical and medical dressing (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide hemostatic wound dressing comprising fabric comprising oxidized regenerated cellulose and polymeric porous matrix comprising water-soluble water-swellaable polymer as claimed by application 10/396,226, and replace the porous water-soluble water-swellaable polymer matrix by porous collagen material disclosed by US '540, motivated by the teaching of US '540 that porous collagen material are useful as surgical and medical dressing because it is mechanically stable comfortable and has high absorptivity, with reasonable expectation of having hemostatic wound dressing comprising fabric comprising oxidized regenerated cellulose

and collagen porous matrix wherein the dressing is mechanically stable comfortable and has highly absorptive.

This is a provisional obviousness-type double patenting rejection.

6. Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 9 of copending Application No. 10/186,021 in view of US 4,948,450 (540). The present claims and the conflicting claims are directed to hemostatic wound dressing comprising fabric comprising oxidized regenerated cellulose and polymeric porous matrix comprising water-soluble water-swellaable polymer.

The difference between the present claims and the conflicting claims of the copending application is that the conflicting claims do not recite the water-soluble water-swellaable polymer as proteinaceous polymer.

US '540 teaches mechanically stable comfortable wound dressing of porous non-cross-linked collagen material that exhibits high absorptivity that makes it useful as surgical and medical dressing (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide hemostatic wound dressing comprising fabric comprising oxidized regenerated cellulose and polymeric porous matrix comprising water-soluble water-swellaable polymer as claimed by application 10/186,021, and replace the porous water-soluble water-swellaable polymer matrix by porous collagen material disclosed by US '540, motivated by the teaching of US '540 that porous

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collagen material are useful as surgical and medical dressing because it is mechanically stable comfortable and has high absorptivity, with reasonable expectation of having hemostatic wound dressing comprising fabric comprising oxidized regenerated cellulose and collagen porous matrix wherein the dressing is mechanically stable comfortable and has highly absorptive.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2,517,772 ('772).

US '772 disclosed bandage or dressing the exceptionally possesses high hemostatic properties comprising fibers of oxidized cellulose. The dressing is impregnated with thrombin and freeze-dried under reduced pressure, i.e. lyophilized (col.1, lines 23; col.2, example 1). Thrombin is protein, and reads on blood protein claimed by claim 4 as a water-soluble water swellable proteinaceous polymer. The references disclosed that fibrous oxidized cellulose impregnated with thrombin, i.e. water-soluble water swellable proteinaceous polymer, are lyophilized and applicants

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disclosed by the present example 1 that porous matrix of proteinaceous polymer is produced by lyophilization of the oxidized cellulose and the proteinaceous polymer. Therefore, the thrombin impregnating the oxidized cellulose fibers inherently forms a porous matrix upon lyophilization. The examples disclosed the oxidized cellulose has carboxyl groups, i.e. carboxyl modified as required by claim 8.

9. Claims 1-4 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,645,849 ('849).

US '849 disclosed hemostatic matrix patch comprising epsilon aminocaproic acid (EACA) impregnated into oxidized regenerated cellulose matrix (abstract; col.3, lines 50-60). EACA reacts on lipoprotein claimed by claim 4 as a water-soluble water swellable proteinaceous polymer. The references disclosed that the matrix of oxidized cellulose fibers and EACA, i.e. water-soluble water swellable proteinaceous polymer, are lyophilized and applicants disclosed by the present example 1 that porous matrix of proteinaceous polymer is produced by lyophilization of the oxidized cellulose and the proteinaceous polymer. Therefore, EACA in the matrix of oxidized cellulose fibers inherently forms a porous matrix upon lyophilization. The hemostatic patch further comprises additional hemostatic agent (col.5, lines 42-43).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '772 in view of US 4,948,540 ('540).

The teachings of US '772 are discussed under 102 rejection above.

However, US '772 does not teach non-cross-linked collagen as a proteinaceous polymer as claimed by claim 5, and additional hemostatic agent as claimed by claim 10.

US '540 teaches mechanically stable comfortable wound dressing of porous non-cross-linked collagen material that exhibits high absorptivity that makes it useful as surgical and medical dressing (abstract). The wound dressing further comprises hemostatic agent (col.4, lines 59-61).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide hemostatic wound dressing comprising oxidized regenerated cellulose fibers and thrombin that have been lyophilized to provide porous matrix as disclosed by any of US '772, and further replace the porous water-soluble water-swellaable polymer matrix by porous non-cross-linked collagen material and further add additional hemostatic material as disclosed by US '540, motivated by the teaching of US '540 that porous collagen material are useful as surgical and medical dressing because it is mechanically stable comfortable and has high absorptivity, with reasonable expectation of having hemostatic wound dressing comprising oxidized regenerated cellulose fibers and non-cross-linked collagen porous matrix and hemostatic agent, wherein the dressing is mechanically stable comfortable and has highly absorptive.

13. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '849, in view of US 4,948,540 ('540).

The teachings of US '849 are discussed under 102 rejection above.

However, US '849 does not teach non-cross-linked collagen as a proteinaceous polymer as claimed by claim 5.

US '540 teaches mechanically stable comfortable wound dressing of porous non-cross-linked collagen material that exhibits high absorptivity that makes it useful as surgical and medical dressing (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide hemostatic wound dressing comprising oxidized

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regenerated cellulose fibers and proteinaceous polymer that have been lyophilized to provide porous matrix as disclosed by US '849, and replace the porous water-soluble water-swellaable polymer matrix by porous non-cross-linked collagen material as disclosed by US '540, motivated by the teaching of US '540 that porous collagen material are useful as surgical and medical dressing because it is mechanically stable comfortable and has high absorptivity, with reasonable expectation of having hemostatic wound dressing comprising oxidized regenerated cellulose fibers and collagen porous matrix wherein the dressing is mechanically stable comfortable and has highly absorptive.

14. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '772 and US '849, each in view of WO 98/00180 ('180).

The teachings of US '772 and US '849 are discussed under 102 rejection above.

However, US '772 and US '849 do not teach the ratio of the proteinaceous polymer to the regenerated cellulose fibers as claimed by claims 6 and 7.

WO '180 teaches wound dressing exhibiting better control of physical and biological absorption rates and better therapeutic effect on the wound healing. The dressing comprising fabric made of fibers of oxidized regenerated cellulose complexed with protein at a ratio of 1:99 to 99.99:1 (abstract; page 3, lines 25-27; page 4, lines 10-15, 32-34; page 5, lines 23-26; page 7, lines 5-6, 17-30). The material is freeze dried to form sponge, i.e. microporous structure (page 5, lines 28-33).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide hemostatic wound dressing comprising oxidized regenerated cellulose fibers and proteinaceous polymer that have been lyophilized to provide porous matrix as disclosed by any of US '772 or US '849, and further adjust the ratio of the oxidized regenerated cellulose fibers and proteinaceous polymer to be between 1:99 to 99.99:1 as disclosed by WO '180, motivated by the teaching of WO '180 such a ratio provided wound dressing exhibiting better control of physical and biological absorption rates and better therapeutic effect on the wound healing, with reasonable expectation of having hemostatic wound dressing comprising oxidized regenerated cellulose fibers and proteinaceous polymer at the ratio between 1:99 to 99.99:1 wherein the wound dressing exhibits better control of physical and biological absorption rates and better therapeutic effect on the wound healing.

15. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '772, in view of US 4,543,410 ('410).

The teachings of US '772 are discussed under 102 rejection above.

However, US '772 does not teach oxidized regenerated cellulose to be aldehyde modified as claimed by claim 9.

US 410 teaches absorbent coherent flexible structure having hemostatic properties in the form of fibrous web and porous sponges comprises aldehyde or carboxylic modified oxidized cellulose that increases the hemostatic efficacy of the

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structures without imparting bioassimilability or bioabsorbability characteristics (abstract; col.1, lines 51-60, 65-68; col.2, lines 30-45; col.9, lines 37-51; col.10, lines 1-20).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide hemostatic wound dressing comprising oxidized regenerated cellulose fibers and proteinaceous polymer that have been lyophilized to provide porous matrix as disclosed by any of US '772, and use aldehyde modified oxidized regenerated cellulose as disclosed by US '410, motivated by the teaching of US '410 that aldehyde and/or carboxylic modification of oxidized cellulose increases the hemostatic efficacy of the structures without imparting bioassimilability or bioabsorbability characteristics of the oxidized cellulose, with reasonable expectation of having hemostatic wound dressing comprising aldehyde and/or carboxylic modified oxidized regenerated cellulose fibers and proteinaceous polymer that has increased hemostatic efficacy without imparting bioabsorbability of the hemostatic dressing.

16. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '849 in view of US 4,543,410 ('410).

The teachings of US '849 and US '410 are discussed above.

However, US '849 does not teach oxidized regenerated cellulose to be carboxylic modified as claimed by claim 8 or aldehyde modified as claimed by claim 9.

US '410 teaches aldehyde and carboxylic modified cellulose as discussed previously.

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Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide hemostatic wound dressing comprising oxidized regenerated cellulose fibers and proteinaceous polymer that have been lyophilized to provide porous matrix as disclosed by any of US '849, and use carboxylic or aldehyde modified oxidized regenerated cellulose as disclosed by US '410, motivated by the teaching of US '410 that carboxylic or aldehyde modification of oxidized cellulose increases the hemostatic efficacy of the oxidized cellulose structures without imparting bioassimilability or bioabsorbability characteristics of the oxidized cellulose, with reasonable expectation of having hemostatic wound dressing comprising carboxylic or aldehyde modified oxidized regenerated cellulose fibers and proteinaceous polymer that has increased hemostatic efficacy without imparting bioabsorbability of the hemostatic dressing.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

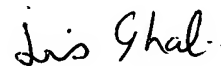
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615

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ISIS GHALI
PRIMARY EXAMINER